

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

HALEEM BONAPARTE;
TINISHA SMITH

Plaintiff,

v.

JOHNSON & JOHNSON CONSUMER,
INC.;

Defendant.

Civil Action No. 2:23-cv-00150-MDL

COMPLAINT

JURY TRIAL REQUESTED

COMPLAINT

Plaintiff Tinisha Smith and Plaintiff Haleem Bonaparte pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through undersigned counsel, bring this Complaint for damages against Defendant JOHNSON & JOHNSON CONSUMER, INC. (hereinafter, "Defendant", "JJCI", "Johnson and Johnson") and in support, state the following:

PRELIMINARY STATEMENT

1. This is an action brought by Haleem Bonaparte and his Mother, Tinisha Smith (herein after "Plaintiffs", "Plaintiff", "Plaintiff Mother", "Plaintiff's Mother", or "Plaintiff Child") arising out of the Defendant's failure to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter, "APAP"). APAP is sold under the tradename Tylenol by Defendants. As a result of Defendant's failure, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and a diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant completely breached its duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated damages.

PARTIES

3. Plaintiffs, at all times relevant in this Action, resided in, and continue to reside in, and are citizens of Berkeley County, South Carolina.

4. Defendant Johnson and Johnson Consumer Inc., is a New Jersey Corporation with its principal place of business located at 199 Grandview Rd Skillman, NJ, 08558.

5. At all times relevant to this action, Defendant Johnson & Johnson designed, tested, developed, manufactured, processed, labeled, marketed, distributed, promoted, and sold APAP to individuals throughout the United States, including South Carolina. At all times relevant hereto, Defendant was engaged in business in South Carolina, has conducted substantial business activities in South Carolina, and derived substantial revenue from within the State of South Carolina. Defendant has also carried on solicitations or service activities in South Carolina.

6. At all times alleged herein, Defendant includes any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all persons acting on their behalf.

JURISDICTION AND VENUE

7. Jurisdiction is proper in this court under 28 U.S.C. § 1332(a)(1) because the Plaintiffs and the Defendant are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars (\$75,000.00), exclusive interest and costs.

8. This Court has personal jurisdiction over Defendant as the claims brought in this Action arise or relate to Defendant's activities within this District. Defendant's activities within this District include the marketing, distribution, advertisement, and sale of medicinal or health related products, particularly Tylenol brand products.
9. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred within this District.

FACTUAL ALLEGATIONS

APAP is Marketed as the Safe Pain Reliever for Pregnant Women, But APAP Can Cause Autism Spectrum Disorder, and Attention-deficit/Hyperactive Disorder

10. APAP is widely used by pregnant women to relieve pain during pregnancy. Common brand or trade names for APAP are Tylenol and Panadol in The United States. Tylenol is produced by Defendants.
11. APAP is one of the most highly used medications in the country with over 25 billion doses of APAP administered annually.¹
12. APAP has long been marketed to pregnant women as the safest pain reliever and fever-reducing drug for use during pregnancy and the only over the counter pain relief drug on the market appropriate for use during pregnancy.²

¹ Manouchehr Saljoughian, ACETAMINOPHEN INTOXICATION: A CRITICAL-CARE EMERGENCY U.S. PHARMACIST – THE LEADING JOURNAL IN PHARMACY (2016), <https://www.uspharmacist.com/article/acetaminophen-intoxication-a-criticalcare-emergency> (last visited Dec 22, 2022).

² Ann Z. Bauer et al., PARACETAMOL USE DURING PREGNANCY - A CALL FOR PRECAUTIONARY ACTION NATURE NEWS (2021), <https://www.nature.com/articles/s41574-021-00553-7> (last visited Dec 22, 2022).

13. Roughly 65% of pregnant women in the United States use APAP during pregnancy.³
14. Despite the above mentioned marketing and the widespread use of APAP, new research shows that prenatal exposure to APAP can alter fetal development and cause birth defects as well as life long disorders. Particularly, these birth defects and disorders include, but are not limited to, Autism Spectrum Disorder ("ASD") and Attention-Deficit/Hyperactivity Disorder ("ADHD").⁴
15. It is vital that a fetal brain remain undisturbed in its development during pregnancy.⁵ If disturbed, a fetal brain can develop improperly.
16. After ingestion by a pregnant woman, APAP is known to readily cross the placenta and blood-brain barrier thus affecting the fetus' brain tissue.⁶
17. ASD is a serious neurological and development disorder that severely alters an individual's cognitive and social abilities.⁷
18. ASD has no cure and lasts a lifetime. Although lifelong, ASD has several treatment options. These treatment options include: behavioral management therapy, cognitive behavior therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill

³ *Id.*

⁴ *Id.*

⁵ Moriah E Thomason, DEVELOPMENT OF BRAIN NETWORKS IN UTERO: RELEVANCE FOR COMMON NEURAL DISORDERS BIOLOGICAL PSYCHIATRY (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7808399/> (last visited Dec 22, 2022).

⁶ Ann Z. Bauer et al., PARACETAMOL USE DURING PREGNANCY - A CALL FOR PRECAUTIONARY ACTION NATURE NEWS (2021), <https://www.nature.com/articles/s41574-021-00553-7> (last visited Dec 22, 2022).

⁷ What is autism spectrum disorder?, CENTERS FOR DISEASE CONTROL AND PREVENTION (2022), <https://www.cdc.gov/ncbddd/autism/facts.html> (last visited Dec 22, 2022).

training, and speech-language therapy.⁸ Unfortunately, the yearly cost of such treatments are estimated to be upwards of \$50,000 yearly.⁹

19. There are three functional levels of ASD, with Level 1 requiring support with activities of daily living, Level 2 requiring substantial support with activities of daily living, and Level 3 requiring very substantial support with activities of daily living.¹⁰
20. ADHD is a chronic neurodevelopment disorder causing attention difficulties, hyperactivity, and impulsiveness. Individuals with this disorder often struggle with academics, work tasks, and impulsive or risky behaviors.¹¹
21. ADHD has no cure and lasts a lifetime. ADHD begins in childhood and persists throughout adulthood. And, as stated earlier, ADHD causes all sorts of issues, including issues with self-esteem, interpersonal relationship conflicts, and difficulties with work and school.¹²

⁸ Treatment and intervention services for autism spectrum disorder, CENTERS FOR DISEASE CONTROL AND PREVENTION (2022), <https://www.cdc.gov/ncbdd/autism/treatment.html> (last visited Dec 22, 2022).

⁹ Autism's cost, BEACON HEALTH OPTIONS, <https://www.beaconhealthoptions.com/autisms-cost#:~:text=A%20recent%20study%20estimates%20the,four%20years%20of%20treatment%3A%20%24240%2C000>. (last visited Dec 22, 2022).

¹⁰ Levels of autism: Symptoms and criteria, MEDICAL NEWS TODAY, <https://www.medicalnewstoday.com/articles/325106#:~:text=According%20to%20the%20Diagnos,tic%20and,communication%20and%20restricted%2C%20repetitive%20behaviors>. (last visited Dec 22, 2022).

¹¹ Adult attention-deficit/hyperactivity disorder (ADHD), MAYO CLINIC (2022), <https://www.mayoclinic.org/diseases-conditions/adult-adhd/symptoms-causes/syc-20350878> (last visited Dec 22, 2022).

¹² What is ADHD?, CENTERS FOR DISEASE CONTROL AND PREVENTION (2022), [https://www.cdc.gov/ncbdd/adhd/facts.html#:~:text=ADHD%20is%20one%20of%20the,\)%2C%20or%20be%20overly%20active](https://www.cdc.gov/ncbdd/adhd/facts.html#:~:text=ADHD%20is%20one%20of%20the,)%2C%20or%20be%20overly%20active). (last visited Dec 22, 2022).

22. Treatments for ADHD include various therapies and chronic medication.¹³ ADHD treatment includes medications that are direct stimulants which have many negative side effects.¹⁴
23. The Center for Disease Control and Prevention estimates that 1 in 44 (2.3%) of 8 year old children have ASD.¹⁵
24. The above number of 1 in 44 is a massive jump when compared to other recorded data. In 2000 and 2002, the autism estimate was about 1 in 150 children. In 2004, this estimate was 1 in 125 in children. In 2006, the autism estimate was 1 in 110 children. Only two years later, the autism estimate was 1 in 88 children.¹⁶
25. As of 2019, 9.8% of children had been diagnosed with ADHD, or roughly 325,000 children per year.¹⁷

¹³ Attention-deficit/hyperactivity disorder (ADHD) in children, MAYO CLINIC (2019), <https://www.mayoclinic.org/diseases-conditions/adhd/diagnosis-treatment/drc-20350895> (last visited Dec 22, 2022).

¹⁴ ADHD medications: How they work & side effects, CLEVELAND CLINIC, <https://my.clevelandclinic.org/health/treatments/11766-adhd-medication> (last visited Dec 22, 2022).

¹⁵ Autism and developmental disabilities monitoring (ADDM) network, CENTERS FOR DISEASE CONTROL AND PREVENTION (2022), <https://www.cdc.gov/ncbddd/autism/addm.html> (last visited Dec 22, 2022).

¹⁶ Miriam Falco, AUTISM RATES NOW 1 IN 68 U.S. CHILDREN: CDC CNN (2014), <https://www.cnn.com/2014/03/27/health/cdc-autism/index.html#:~:text=Story%20highlights&text=One%20in%2068%20U.S.%20children,for%20Disease%20Control%20and%20Prevention>. (last visited Dec 22, 2022).

¹⁷ Data and statistics about ADHD, CENTERS FOR DISEASE CONTROL AND PREVENTION (2022), <https://www.cdc.gov/ncbddd/adhd/data.html> (last visited Dec 22, 2022).

26. Parental awareness and changes in diagnoses do not account for the rapid rise in ADHD and ASD diagnoses.¹⁸
27. Rather, neurotoxic exposures, such as prenatal APAP exposure, explain a trending increase in diagnosis.¹⁹
28. For years, the scientific community has published studies showing that prenatal ingestion of APAP can cause ASD and ADHD.²⁰
29. Since 2013, there have been six European birth cohort studies, examining over 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and ADHD.²¹
30. The overall body of scientific evidence has shown that a mother's prenatal use of APAP can cause ASD and ADHD in the child.
31. During all relevant times herein, Defendant was engaged in the business of manufacturing and selling the APAP Products in the United States, and the weight of the scientific evidence

¹⁸ Why the increase in autism (ASD), ADHD and neurodevelopmental disorders?, AUSTRALIAN AUTISM ADHD FOUNDATION LIMITED, https://www.autism-adhd.org.au/autism_prevalence#:~:text=Recent%20research%20suggests%20that%20these,7%5D%2C%20and%20other%20chemicals. (last visited Dec 22, 2022).

¹⁹ Ilona Quaak, Madeleine R Brouns & Margot Van de Bor, THE DYNAMICS OF AUTISM SPECTRUM DISORDERS: HOW NEUROTOXIC COMPOUNDS AND NEUROTRANSMITTERS INTERACT INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3774444/> (last visited Dec 22, 2022).

²⁰ NIH-funded study suggests acetaminophen exposure in pregnancy linked to higher risk of ADHD, autism, NATIONAL INSTITUTES OF HEALTH (2019), <https://www.nih.gov/news-events/news-releases/nih-funded-study-suggests-acetaminophen-exposure-pregnancy-linked-higher-risk-adhd-autism> (last visited Dec 22, 2022).

²¹ Alemany et. Al.; PRENATAL AND POSTNATAL EXPOSURE TO ACETAMINOPHEN IN RELATION TO AUTISM SPECTRUM AND ATTENTION-DEFICIT AND HYPERACTIVITY SYMPTOMS IN CHILDHOOD: META-ANALYSIS IN SIX EUROPEAN POPULATION-BASED COHORTS EUROPEAN JOURNAL OF EPIDEMIOLOGY, <https://pubmed.ncbi.nlm.nih.gov/34046850/> (last visited Dec 22, 2022).

available showed prenatal exposure to APAP significantly increases the risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD and ADHD.

32. At the time Plaintiff Mother was pregnant with Plaintiff Child, the scientific evidence regarding the risks of in utero exposure of APAP was available to Defendant, and Defendant knew or should have known that prenatal use of APAP can cause ASD or ADHD.
33. Based on information and belief, Defendant has concealed the prenatal APAP exposure-neurodevelopmental link from consumers, like Plaintiff Mother.
34. Moreover, despite knowing that prenatal use of APAP can cause ASD or ADHD, Defendant continued, and continues, to market APAP Products as safe pain relievers for pregnant women, making mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

**Plaintiff's Mother Ingested APAP While Pregnant and This Ingestion Caused ADHD in
Plaintiff Child**

35. Plaintiff's Mother began using the APAP products in or around March of 2003 when pregnant with Plaintiff Child.
36. Over the course of her pregnancy, Plaintiff's Mother took APAP products for pain relief multiple times per week.
37. Plaintiff's Mother fully believed that it was safe for her to ingest the APAP Products while pregnant.
38. Plaintiff's Mother was specifically instructed to avoid other pain medications such as ibuprofen or aspirin when pregnant, but was informed that she could take APAP medications without risk.

39. There is no warning on the APAP Products' labels or packing specifically addressing the risks of ASD or ADHD if a mother ingests APAP while pregnant.
40. Had Plaintiff's Mother known of the risks in ingesting APAP, specifically those related to ASD or ADHD, she would not have ingested APAP products.
41. Plaintiff Bonaparte was born on January 16, 2004.
42. In 2009, Plaintiff Bonaparte was diagnosed with ASD and is given medicine and therapy to treat the ASD.
43. Throughout elementary and middle school, Plaintiff Bonaparte was placed in different classes than his non-ASD suffering peers. Plaintiff was given an Individualized Education Plan by his respective schools.
44. Plaintiff Child's ADHD/ASD puts an incredible emotional and financial strain on Plaintiff Mother and other family members. Plaintiff Mother fears for Plaintiff Child and has anxiety due to the challenges associated with Plaintiff Child's ADHD/ASD.

ESTOPPEL AND TOLLING STATUTE OF LIMITATIONS

45. Due to the Defendant's acts of fraudulent concealment, Defendant is estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiff Mother and the general public that APAP is defective and harmful when exposed to fetuses in utero while continuing to market the APAP Products with the adverse effects described in this Complaint.
46. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to it, but not the public, and because Plaintiff Mother could not reasonably know that the APAP Products were defective, Defendant is estopped from relying on statutes of limitations that may be applicable to the claims asserted in this Complaint.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY FAILURE TO WARN

47. Plaintiff realleges and incorporates by reference every allegation contained in the foregoing as if fully set forth herein.
48. At the time of Plaintiff's injuries, the APAP Products were defective and unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable manner during pregnancy, including Plaintiff mother, because they lacked an adequate warning.
49. At all relevant times, Defendant engaged in the business of designing, testing, developing, manufacturing, processing, labeling, distributing, promoting, and selling the defective APAP Products. These APAP Products were dangerous and defective because they did not contain adequate warnings or instructions concerning the dangerous characteristics and risks of ingesting APAP during pregnancy. The actions listed above were under the ultimate control and supervision of Defendant.
50. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP Products within this District and aimed the marketing at the ultimate consumer.
51. Defendant had a duty to warn of the risks associated with the use of APAP Products during pregnancy. Defendant breached its duty because it did not warn of such risks.
52. The APAP Products ingested by Plaintiff's Mother during pregnancy were in the same or substantially similar condition as they were when they left the possession of Defendant.

53. Defendant expected and intended the APAP Products to reach users such as Plaintiff Mother in the condition in which the APAP Products were sold.
54. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.
55. Plaintiff's Mother ingested the APAP Products during pregnancy as indicated on the APAP Products' label and packaging.
56. The labels on the APAP products lack any warning specific to pregnant women. The information that Defendant did provide or communicate to consumers failed to contain relevant warnings, hazards, and precautions that would have enabled consumers to utilize the Products safely, or to decide to not use or ingest the APAP Products at all.
57. This failure to warn is not limited to the information contained on the APAP Products' labeling. Defendant was able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with exposure to or use of APAP Products during pregnancy through other non-labeling mediums, including, but not limited to, promotion, advertisements, public service announcements, and/or public information sources. Although available, Defendant did disclose these risks through any medium.
58. At all times relevant, Defendant had a duty to test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply APAP Products; provide proper warnings for the APAP Products; and take such steps as necessary to ensure the APAP Products did not cause users and consumers, and their children to suffer from unreasonable and dangerous risks properly and safely. Defendants had a continuing duty to warn Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy. Defendants, as manufacturers, sellers, and distributors of pharmaceutical medication, are held to the knowledge of an expert in the field.

59. At the time of manufacture, Defendant could have provided warnings or instructions regarding the full and complete risks of the APAP Products during pregnancy of the APAP Products during pregnancy because Defendant knew or should have known of the unreasonable risks of ASD and ADHD related to prenatal exposure or use of such APAP Products.

60. At all times relevant, Defendant failed and deliberately refused to investigate, study, test, or promote the safety of the APAP Products, or to minimize the dangers to consumers of the APAP Products and to those who would foreseeably use or be harmed by the APAP Products, including Plaintiffs.

61. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the significant increased risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD and ADHD.

62. Defendant failed to adequately inform reasonably foreseeable consumers, like Plaintiff's Mother, of the proper usage of the APAP Products.

63. Even though Defendant knew or should have known that APAP posed a grave risk of harm to Plaintiff Bonaparte, Defendant failed to exercise reasonable care to warn of the dangerous risks associated with use and prenatal exposure.

64. Plaintiff's Mother was exposed to the APAP Products during pregnancy without knowledge of APAP's dangerous characteristics.

65. At all relevant times, Plaintiff's Mother used and/or was exposed to the use of the APAP Products while using them for their intended or reasonably foreseeable purposes during pregnancy, without knowledge of their dangerous characteristics.

66. Plaintiff's Mother could not have reasonably discovered the defects and risks

associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of Defendant to know about and disclose serious health risks associated with using the APAP Products.

67. If Plaintiff's Mother had been properly warned of the defects, dangers, and risks associated with prenatal exposure to APAP, Plaintiff's Mother would have utilized the APAP Products safely and with adequate protection during pregnancy or would have decided to not ingest the APAP Products at all. Defendant's failure to properly warn of those defects, dangers, and risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs' injuries and damages.

68. Defendant is liable to Plaintiff for injuries caused by Defendant's negligent or willful failure, as described above, to provide adequate warnings or other relevant information and data regarding the appropriate use of the APAP Products and the risks associated with the use of APAP.

69. As a direct and proximate result of Defendant placing defective APAP Products into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing her to develop ADHD.

70. As a direct and proximate result of Defendant placing defective APAP Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT II: NEGLIGENCE

71. Plaintiffs reallege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

72. Although Defendant had a duty to use reasonable care in testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing written instructions and warnings for the APAP Products, Defendant failed to do so.

73. Defendant, directly or indirectly, caused the APAP Products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff's Mother. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, promoted, and sold the APAP Products within this district and aimed at a consumer market within this district.

74. Defendant knew, or in the exercise of reasonable care should have known, that the APAP Products were defectively and unreasonably designed and/or manufactured, and/or marketed, and were unreasonably dangerous and likely to injure persons that were prenatally exposed to them. Defendant knew or should have known that Plaintiff's Mother was unaware of the dangers and defects inherent in the APAP Products when she was ingesting them during her pregnancy with Plaintiff Child.

75. At all relevant times, Defendant had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the APAP Products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using APAP during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of APAP and, in particular, the significantly increased risk of causing neurodevelopmental disorders in

children through prenatal exposure to APAP.

76. At all relevant times, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of APAP ingestion while pregnant and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

77. Defendant failed to provide any kind of warning to pregnant consumers, like Plaintiff's Mother, about the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

78. Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable care, should have known that use of the APAP Products during pregnancy could cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

79. As such, Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, labeling, supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in that Defendant manufactured and produced defective APAP Products, which carry the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP Products; knew or had reason to know that a user's or consumer's use of the APAP Products during pregnancy created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

80. Defendant had a duty to disclose the truth about the risks associated with exposure to or use of APAP during pregnancy in its promotional efforts outside of the context

of labeling. Defendant was negligent in its promotion of APAP outside of the labeling context by failing to disclose material risk information as part of its promotion and marketing of the APAP Products, including through the internet, television, and print advertisements.

81. Despite Defendant's ability and means to investigate, study, and test the APAP Products and to provide adequate warnings regarding use during pregnancy, Defendant failed to do so. Indeed, Defendant wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of APAP.

82. Defendant's negligence included:

- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the APAP Products while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;
- b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the APAP Products were safe for its intended consumer use and unborn children; and
- c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would use the APAP Products during pregnancy; and
- d. Failing to disclose to Plaintiff's Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks

- of neurodevelopmental disorders in children exposed to APAP prenatally; and
- e. Failing to warn Plaintiff's Mother, users, consumers, and the general public that the APAP Products' risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers; and
 - f. Representing that the APAP Products were safe for their intended purposes for pregnant women when, in fact, Defendant knew or should have known the APAP Products were not safe for their intended purposes; and
 - g. Declining to make or propose any changes to the APAP Products' labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women; and
 - h. Advertising, marketing, and recommending the use of the APAP Products during pregnancy, while concealing and failing to disclose or warn of the dangers known by Defendant to be caused by the use of or exposure to APAP; and
 - i. Continuing to disseminate information to its consumers and the general public, which indicates or implies that the APAP Products are not unsafe for pregnant consumer use; and
 - j. Continuing the manufacture and sale of the APAP Products with the knowledge that the APAP Products were unreasonably unsafe and

dangerous.

83. Defendant knew and/or should have known that it was foreseeable that children such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP Products to pregnant consumers, like Plaintiff Mother.

84. Plaintiff's Mother did not know the nature and extent of the injuries that could result in her child from the intended use of and/or exposure to APAP prenatally.

85. Defendant's negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendant's negligence, Plaintiff Child would not have developed ADHD or ASD.

86. Defendant's conduct, as described above, was reckless. Defendant regularly risked exposing Plaintiff's Mother to the APAP Products while pregnant with Plaintiff Child, with full knowledge of the dangers of the APAP Products and that it could cause ASD and ADHD in Plaintiff Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff's Mother. Defendant's reckless conduct therefore warrants an award of punitive damages.

87. As a direct and proximate result of Defendant placing the defective APAP Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT III: BREACH OF EXPRESS WARRANTY

88. Plaintiffs reallege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

89. At all material times, Defendant manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the APAP Products. These actions were under the ultimate control and supervision of Defendant.

90. In advertising, marketing, and promoting the APAP Products to consumers, like Plaintiff's Mother, Defendant expressly warranted that the APAP Products were safe for use and reasonably fit for their intended purposes, including ingestion by pregnant persons. In advertising, marketing, and otherwise promoting the APAP Products, Defendant intended for pregnant consumers to rely upon its representations regarding safety and fitness, in an effort to induce them to purchase and consume the APAP Products during pregnancy to relieve pain.

91. Defendant expressly warranted to Plaintiff's Mother and pregnant consumers that the APAP Products were safe for ingestion during pregnancy.

92. Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the APAP Products, including a duty to:

- a. ensure that the APAP Products during pregnancy did not cause users and their unborn children unreasonably dangerous side effects;
- b. warn of dangerous and potentially incurable side effects; and
- c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

93. Defendant had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

94. At all relevant times, Defendant expressly represented and warranted to the purchasers of the APAP Products, by and through statements made by Defendant in labels, publications, brochures, and other written materials intended for consumers and the general public, that the APAP Products were safe to human health and the environment, effective, fit, and proper for their intended use during pregnancy. Defendant advertised, labeled, marketed, and promoted the APAP Products, representing the quality to consumers and the public in such a way as to induce their purchases or use during pregnancy, thereby making an express warranty that the APAP Products would conform to the representations.

95. The representations about the APAP Products, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

96. Defendant breached express representations and warranties made to Plaintiff's Mother, with respect to the APAP Products, including the following:

- a. Defendant represented through its labeling, advertising, and marketing materials that the APAP Products were safe for use during pregnancy, and intentionally withheld and concealed information about the risks of serious injury associated with use of APAP and by expressly limiting the risks associated with use during pregnancy within its warnings and labels; and
- b. Defendant represented that the APAP Products were safe for use and intentionally concealed information that demonstrated that APAP carries the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and that the APAP Products, therefore, were not safer than

alternatives available on the market.

97. Plaintiff's Mother detrimentally relied on the express warranties and representations of Defendant concerning the safety and/or risk profile of APAP during pregnancy in deciding to purchase the APAP Products. Plaintiff's Mother reasonably relied upon Defendant to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff's Mother would not have purchased or used the APAP Products during pregnancy had Defendant properly disclosed the risks associated with the APAP Products, either through advertising, labeling, or any other form of disclosure. Defendant's breach of the express warranties and representations concerning the safety and/or risk profile of APAP during pregnancy was a substantial factor in causing Plaintiffs' injuries and damages.

98. Plaintiff's Mother had no knowledge of the falsity or incompleteness of Defendant's statements and representations concerning the APAP Products and could not have taken reasonable steps to notify Defendant of those matters or to seek repair or other remedies.

99. Plaintiff's Mother used and/or was exposed to APAP during pregnancy as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendant.

100. Had the warnings, labels, advertisements, or promotional material for the APAP Products accurately and adequately set forth the true risks associated with the use of such Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the APAP Products were safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

101. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT IV: BREACH OF IMPLIED WARRANTY

102. Plaintiffs reallege and incorporate by reference each allegation contained in the foregoing paragraphs as though fully set forth herein.

103. At all material times, Defendant manufactured, marketed, sold, distributed, and otherwise placed the APAP Products into the stream of commerce.

104. At all material times, Defendant intended for the APAP Products to be consumed and ingested by pregnant persons, like Plaintiff Mother; and Defendant impliedly warranted that the APAP Products and their component parts were of merchantable quality, safe, fit for such use, and adequately tested.

105. Defendant was aware that consumers, including Plaintiff Mother, would consume and ingest the APAP Products as directed by the Products' labels and promotional materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP Products.

106. But Defendant failed to disclose that APAP has dangerous propensities when used as intended during pregnancy and that use of the APAP Products carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

107. The APAP Products were expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendant.

108. Plaintiff Mother was an intended beneficiary of the implied warranties made

by Defendant to purchasers of the APAP Products, including Plaintiff's Mother.

109. In reliance upon Defendant's implied warranties, Plaintiff's Mother purchased and used the APAP Products as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant. The failure of the APAP Products to be of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a substantial factor in causing Plaintiffs' injuries and damages.

110. Defendant breached its implied warranties to Plaintiffs in that the APAP Products were not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

111. The harm caused by the APAP Products far outweighed their benefit, rendering the APAP Products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

112. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT V: NEGLIGENT MISREPRESENTATION

113. Plaintiffs reallege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

114. Defendant had a duty to represent to consumers, including Plaintiff Mother, that the APAP Products had not been adequately tested and found to be a safe and effective treatment accurately and truthfully for pregnant women. Defendant breached that duty as its representations of the safety of the APAP Products were false. Defendant intended for

consumers like Plaintiff Mother to rely upon that representation, Plaintiff Mother did justifiably rely on Defendant's misrepresentations concerning the APAP Products' high risk of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

115. Defendant failed to exercise ordinary care in the representations concerning the APAP Products while Defendant was involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendant negligently misrepresented the APAP Products' high risk of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

116. Defendant also breached its duty in representing to Plaintiff Mother that the APAP Products had no serious side effects when ingested during pregnancy. Defendant intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff Mother did justifiably rely upon that representation.

117. Defendant knew or had reason to know that the APAP Products had been insufficiently tested or had not been tested at all; and that they lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk, of adverse side effects. Those side effects include neurodevelopmental disorders in children, such as ASD and ADHD. Thus, Defendant lacked reasonable ground for believing the representations to be true and intended for consumers like Plaintiff to rely upon those misrepresentations by purchasing the APAP products for use during pregnancy. Plaintiff Mother justifiably relied upon those misrepresentations in purchasing and using the APAP products while pregnant. Defendant's negligent misrepresentations concerning the safety and/or risk profile of using APAP during pregnancy was a substantial factor in causing Plaintiffs' injuries and damages.

118. As a direct and proximate result of Defendant's negligent misrepresentation, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT VI: VIOLATION OF CONSUMER PROTECTION LAWS

119. Plaintiffs reallege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

120. Plaintiff Mother purchased and used the APAP Products for primarily personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

121. Had Defendant not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the APAP Products, and Plaintiffs would not have incurred related injury medical costs.

122. Defendant engaged in wrongful conduct and unlawful while at the same time obtaining under false pretenses moneys from Plaintiff for the APAP Products. Those moneys would not have been paid had Defendant not engaged in unfair and deceptive conduct. Plaintiffs actually relied upon Defendant's misrepresentations and deception concerning the APAP Products.

123. Defendant engaged in the following unfair methods of competition or deceptive acts or practices, which are proscribed by law:

- a. representing that goods or services have characteristics, ingredients, uses, benefits, or qualities they do not have; and
- b. advertising goods or services with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct creating a likelihood of confusion or misunderstanding.

124. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The cumulative effect, directed at patients, physicians, and consumers, was to create demand for and sell the APAP Products. Each aspect of Defendant's conduct combined to artificially create sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP Products.

125. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the APAP Products.

126. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

127. Defendant's actions, as complained of in this Complaint, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of the federal and state consumer protection statutes listed below.

128. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade practices, or has made false representations under the following statutes:

- 15 U.S.C. §§ 2301-12 (1982);
- S.C. Code Ann. § 39-5-20 (2020).

129. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendant, as the supplier, manufacturer,

advertiser, and seller, is subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices. The South Carolina Unfair Trade Practices Act renders unlawful “unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” S.C. Code Ann. § 39-5-20 (2020).

130. By knowingly and falsely representing that the APAP Products were fit to be used for the purposes for which they were intended—when in fact they were defective and dangerous when used during pregnancy—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

131. Defendant’s actions and omissions are uncured or incurable, deceptive acts under the above legislation.

132. Defendant had actual knowledge of the defective and dangerous conditions of the APAP products but failed to take any action to cure such defective and dangerous conditions.

133. Plaintiff Mother relied upon Defendant’s misrepresentations and omissions in determining which APAP Products (if any) to ingest.

134. Defendant’s deceptive, unconscionable, or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

135. By reason of the unlawful acts in which Defendant engaged, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

136. As a direct and proximate result of Defendant’s violations of the above-listed legislation, Plaintiffs have sustained economic losses and other damages and are entitled to

statutory and compensatory damages, including restitution, in an amount to be proven at trial and civil penalties as permitted by law.

PUNITIVE DAMAGES

137. Plaintiffs reallege and incorporate by reference each allegation contained in the foregoing paragraphs as though fully set forth herein.
138. Defendant has acted with malice through despicable conduct that exhibits a willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard of their rights. Further, Defendant has intentionally misrepresented or concealed material facts known to it with the intention of causing injury or otherwise depriving Plaintiffs of their property or legal rights.
139. Defendant failed to adequately test and study the APAP Products to determine and ensure that the APAP Products were safe and effective for use during pregnancy before releasing them for sale for human consumption.
140. Further, Defendant continued to manufacture and sell the APAP Products and marketed them for use during pregnancy, even after obtaining knowledge and information that the APAP Products were defective and unreasonably unsafe because they, among other things, did not include adequate warnings.
141. Defendant was aware of the probable consequences of the dangerous and defective product, including the risk of neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered prenatal exposure.
142. At all material times, Defendant knew or should have known that the APAP Products were inherently dangerous with respect to the following: the risk of neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered

prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to cure the conditions proximately related to the use of the APAP Products, as well as the other permanent and lasting severe personal injuries.

143. Defendant knowingly withheld material information from consumers and the public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which to make a fully informed decision about whether to use the APAP Products while pregnant.

144. At all material times, Defendant also knew and recklessly and/or intentionally disregarded the fact that the APAP Products, when used during pregnancy, can cause debilitating and life-altering side effects with greater frequency than safer alternative methods, products, and/or treatments. But Defendant recklessly failed to advise the medical community and the general public, including Plaintiff Mother, of that fact.

145. At all material times, Defendant intentionally misstated and misrepresented data; and Defendant continues to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the APAP Products.

146. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the APAP Products, with their increased risk of side effects and serious complications, Defendant continues to aggressively market the APAP Products to consumers, including the pregnant community at large, without disclosing the true risk of the complications and side effects.

147. When Plaintiff Mother consumed the APAP Products and since then, Defendant has known the APAP Products were defective and unreasonably dangerous

without an adequate warning. But Defendant continued to manufacture, produce, assemble, market, distribute, and sell the APAP Products to the pregnant community to maximize sales and profits at the expense of the health and safety of expecting mothers in a conscious, reckless, and/or intentional disregard of the likely and foreseeable harm caused by the APAP Products to members of the public, including Plaintiffs.

148. At all material times, Defendant has concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the APAP Products, to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiffs.

149. Defendant's acts and omissions are of such character and nature to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common law. Defendant's conduct shows malice, oppression, or fraud, or that entire want of care, raising the presumption of conscious indifference to consequences of that conduct, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendant individually, and jointly and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant, individually, and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiffs for past, present, and future damages,

including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law; and

- ii. Restitution and disgorgement of Defendant's profits; and
- iii. Applicable statutory penalties; and
- iv. Punitive or enhanced damages; and
- v. Reasonable attorneys' fees as provided by law; and
- vi. Past and future costs of all proceedings; and
- vii. All ascertainable economic damages; and
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: January 11, 2023

Respectfully submitted,

/s/Paul J. Doolittle
Paul J. Doolittle (Fed ID #6012)
Blake G. Abbott (Fed ID #13354)
POULIN | WILLEY |
ANASTOPOULO, LLC
32 Ann Street
Charleston, SC 29403
Tel: (843) 614-8888
Email: pauld@akimlawfirm.com
blake@akimlawfirm.com

